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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/848,735	05/19/2004	Kevin T. Schomacker	MDS-033C1	7328
51414	7590	03/23/2006	EXAMINER	
GOODWIN PROCTER LLP PATENT ADMINISTRATOR EXCHANGE PLACE BOSTON, MA 02109-2881			SUNG, CHRISTINE	
			ART UNIT	PAPER NUMBER
			2884	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/848,735

Applicant(s)

SCHOMACKER ET AL.

Examiner

Christine Sung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 47-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 47-57, 60-61, 64-66 and 68-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Fulghum US Pre Grant Publication 2003/0232445 A1).

Regarding claim 47, Fulghum discloses an apparatus for determining a condition of a region of a tissue sample (figure 8), the apparatus comprising:

Illuminating optics (element 802) for illuminating a region of a tissue sample (element 805) with electromagnetic radiation incident at a first angle and for illumination the region of the tissue sample with electromagnetic radiation incident at a second angle (see radiation emanating out of element 802);

Collecting optics for collecting electromagnetic radiation from the region of the tissue sample(elements 806); and

A processor (claim 1, “data processor”) adapted to determine a condition of the determine a condition of the region of the tissue sample using representative data selected from at least one of:

A first set of spectral data corresponding to the collected radiation form the region during illumination with radiation incident at the first angle (claim 49);

and a second set of spectral data corresponding to the collected radiation from the region during illumination with radiation incident at the second angle (Claim 49).

Regarding claim 48, Fulghum discloses that the processor is adapted to select representative data based on a subset of the first and second sets of spectral data (paragraph [105]).

Regarding claim 49, Fulghum discloses that the first set comprises reflectance spectral data and the second set comprises reflectance spectral data (paragraph [0020]).

Regarding claim 50, Fulghum discloses that the first set of spectral data and the second set comprises fluorescence data (paragraph [0020]).

Regarding claims 51 and 52, Fulghum discloses determining whether the tissue is cancerous (paragraphs [0016] and [0063]).

Regarding claim 53, Fulghum discloses that the tissue is gastro-esophageal tissue (paragraph [0016]).

Regarding claims 54-55, Fulghum discloses that the tissue sample comprises epithelial cells (claim 52).

Regarding claim 56, Fulghum discloses an apparatus for determining whether spectral data obtained from a region of a tissue sample (figure 8) are affected by an artifact (paragraph [0015]), the apparatus comprising:

Illuminating optics (element 802) for illuminating a region of a tissue sample (element 805) with electromagnetic radiation incident at a first angle and for illuminating the region of the tissue sample with electromagnetic radiation incident at a second angle (see radiation emanating out of element 802);

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Collecting optics for collecting electromagnetic radiation from the region of the tissue sample(elements 806); and

A processor (claim 1, "data processor") adapted to:

Obtain a first set of reflectance spectral data (paragraph [0020]) corresponding to collected radiation from a region during illumination of the region with radiation at a first angle (claim 49);

Obtain a second set of spectral data corresponding to collected radiation from the region during illumination of the region with radiation at a second angle (claim 49);

And determine whether the first set of spectral data is affected by an artifact or field distortion based at least in part on a subset of the first set of spectral data and a subset of the second spectral data (paragraph [0105]).

Regarding claim 57 and 60-61, Fulghum discloses that the artifact comprises a light artifact which is blood (paragraph [0105]).

Regarding claim 64, Fulghum discloses that the first and second sets of spectral data are reflectance data (paragraph [0020]).

Regarding claim 65, Fulghum discloses that the processor is further adapted to obtain a third set of spectral data (paragraph [0105], Fulghum discloses up to seven sets of spectral data)), and wherein the third set of spectral data comprises fluorescence data (paragraph [0020]).

Regarding claim 66, Fulghum discloses that the processor computes a difference in data between the first and second set that are collected from the same wavelength (paragraph [0097]).

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Regarding claim 68, Fulghum discloses an apparatus for determining whether spectral data obtained from a region of a tissue sample (figure 8) are affected by an artifact (paragraph[0015]), the apparatus comprising:

Illuminating optics (element 802) for illuminating a region of a tissue sample (element 805) with electromagnetic radiation incident at a first angle and for illumination the region of the tissue sample with electromagnetic radiation incident at a second angle (see radiation emanating out of element 802);

Collecting optics for collecting electromagnetic radiation from the region of the tissue sample(elements 806); and

A processor (claim 1, “data processor”) adapted to:

Obtain a first set of reflectance spectral data (paragraph [0020]) corresponding to collected radiation from a region during illumination of the region with radiation at a first angle (claim 49);

Obtain a second set of spectral data corresponding to collected radiation form the region during illumination of the region with radiation at a second angle (claim 49);

Obtain a set of fluorescence spectral data corresponding to the region (paragraph [0020]);  
determine whether the first set of spectral data, second spectral data and the fluorescence data is affected by an artifact or field distortion based at lest in part on a subset of the first set of spectral data and a subset of the second spectral data (paragraph [0105]).

Regarding claim 69, Fulghum discloses an apparatus for determining a characteristic of a region of a tissue sample (figure 8), the apparatus comprising:

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Illuminating optics (element 802) for illuminating a region of a tissue sample (element 805) with electromagnetic radiation incident at a first angle and for illumination the region of the tissue sample with electromagnetic radiation incident at a second angle (see radiation emanating out of element 802);

Collecting optics for collecting electromagnetic radiation from the region of the tissue sample(elements 806); and

A processor (claim 1, “data processor”) adapted to:

Obtain a first set of reflectance spectral data (paragraph [0020]) corresponding to collected radiation from a region during illumination of the region with radiation at a first angle (claim 49);

Obtain a second set of reflectance data corresponding to collected radiation form the region during illumination of the region with radiation at a second angle (claim 49);

And determine whether the first set of reflectance data and a second set is affected by an artifact or field distortion based at lest in part on a subset of the first set of reflectance data and a subset of the second spectral data (paragraph [0105]);

Reject at least one member of at least one of the firs set of reflectance and the second set of reflectance determined to be affected by the artifact (subtracts the data contributed by the artifact, paragraph [0105]) ; and

Determine a characteristic of the region of the tissue sample base date least in part or on at least one member of at least one of the first set of reflectance data and the second set of reflectance data not rejected (paragraph [0063]).

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Regarding claim 70, Fulghum further discloses that the processor is adapted to obtain a set of fluorescence spectral data (paragraph [0020]) corresponding to collected radiation from the region (claim 49);

To determine the condition of the region of the tissue sample based at least in part on at least one member of at least one of the first set of reflectance data and the second set of reflectance data and at least one member of the fluorescence spectral data (paragraph [0105]).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 58-59, 62-63 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulghum US Pre Grant Publication 2003/0232445 A1).

Regarding claims 58-59 and 62-63, Fulghum discloses that artifacts or field distortions such as hemoglobin or blood affect the collected data (paragraph [0105]). Although Fulghum



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does not explicitly disclose the claimed artifacts (glare, shadow, speculum, smoke tube, or mucous), such artifacts are known to negatively affect data detected. One of ordinary skill in the art would be motivated to remove or correct for such artifacts in order to increase the accuracy in determining the condition of the tissue.

Regarding claim 67, Fulghum discloses determining the difference in data (paragraph [0097]) but does not specify a percent difference. However, one of ordinary skill in the art would be motivated to use a simple mathematical calculation to determine percent difference in order to easily compare subsequent spectral data.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Sung whose telephone number is 571-272-2448. The examiner can normally be reached on Monday- Friday 7-3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on 571-272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christine Sung

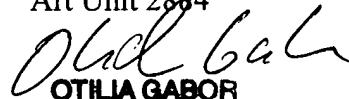
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Examiner  
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**OTILIA GABOR**  
**PRIMARY EXAMINER**